From: Neustifter - CDPHE, Jeremy
To: Olson, Kyle
Subject: Re: EtO Follow-up
Date: Tuesday, January 29, 2019 11:28:25 AM

Hi Kyle,

No problem and glad to have you good folks back at work. Below you'll find our response which was sent at the beginning of the month.

Allie Bamber finalized answers and sent return email 1/2/2019

Hello Allie

It was nice speaking to you today. I am part of the Science Team for the public effort on ethylene oxide in the Willowbrook Illinois area. I worked in the past for Argonne National Laboratory in this field in years past. Argonne is about 1 mile from Willowbrook Illinois.

We are very pleased to be able to learn from your experience with Terumo BCT. We are going through serious problems with ethylene oxide from Sterigenics Willowbrook. Here is the list of questions we had after reading your two Terumo BCT reports:

1. Do you know yet which contractor will carry out your planned stack emission tests for ethylene oxide? If not, is there an approved list of contractors that we could see? We saw on page 2 of the Colorado Air Pollution Control Division report that “Actual post-control emissions modeling will be performed at a later date upon receipt of new stack test emissions information.” We wish to recommend and argue for a qualified laboratory that is not chosen by the Source.

APCD response: The state of Colorado does not dictate which source testing company should be used for a given test program; however we do maintain a list of local contractors for industry and the public to use if they wish. For that list, please see https://environmentalrecords.colorado.gov/HPRMWebDrawer/RecordView/1235393 . Terumo BCT selected Montrose Environmental to conduct their sampling. The emission testing was not required by APCD as Terumo BCT is meeting all their permit requirements, but testing was performed per a request from the department to better understand the efficiency of the voluntary controls which were installed in response to the release of the NATA. We are familiar with the consultant that was hired, and we reviewed their sampling protocols prior to testing. APCD worked closely with the facility and contractor during the process to ensure testing was performed in a manner consistent with what would be required for a compliance test. We do not have the data yet, but all the stack testing, to our knowledge, has now been completed and the data are being compiled into a final report for the Department.

2. How does Colorado handle cases in which, after all mitigation that could be done is done, there is still cancer risk at residences (e.g., Maximally Exposed Individual resident) of more than 100 cancers per 1 million people? Cut back in operations?

Shutdown?
APCD response: Under the Clean Air Act there are no ambient air quality standards for hazardous air pollutants, such as ethylene oxide. Hazardous air pollutants are controlled through the Maximum Achievable Control Technology standards, which are established by the EPA and enforced, in most cases, by the states. Terumo BCT has consistently demonstrated compliance with the MACT standard for ethylene oxide sterilization facilities. The updated NATA reflecting the newly established cancer risk threshold for ethylene oxide is a unique situation for us, and as such, it was evaluated as a case-specific situation.. The APCD does not currently have any provisions in its permitting rules to model cancer risks from the emissions of a facility, but in this case, we felt that it was necessary to model and subsequently monitor for cancer risk in the community surrounding Terumo BCT. Also, considering the potential cancer risks which were shown by the updated NATA in this case, the Department worked closely with the facility to determine what could be done above and beyond what is required by the MACT standard to further reduce emissions and implement those control measures as quickly as possible. The APCD will continue to work with the facility to determine if any other control measures are feasible to even further reduce emissions.

3. The issue of Trans-2-butane affected us in the EPA measurements as it did to you. How did this error come up and which organization discovered it? Your lab Eastern Research Group says that in past data taken in 2018, the average of the trans-2-butane was 0.06 ppbv (Page 3 of Colorado Air Pollution Control Division report). Do you know the spread or standard deviation? We wish to get an idea what the spread was over all measurements taken by ERG in 2018 as we might wish to use the 0.06 ppbv as well to put perspective on the EPA measured field data at Willowbrook.
APCD response: We don't know who originally discovered the issue, but it was brought to our attention by EPA Region 8. We do know that EPA OAQPS has been involved in the issue, and they may have been the ones who discovered the issue. ERG did not provide a spread/standard deviation of the data to us, only the average and the percent detected. Julie Swift (919-468-7924, julie.swift@erg.com) at ERG should be able to provide additional information. For monitoring that we perform every 6th day in downtown Denver, the lab we use (Atmospheric Analysis and Consulting) has reported 4 detections of trans-2-butene out of 50 samples for Jan-Oct 2018. The detections were 0.24, 0.42, 0.45, and 0.61 ppb, with an MDL of 0.10 ppb.

4. How do you handle background levels of ethylene oxide in your regulatory system? How are they considered in risk assessment? We were told that California does not consider background data in source compliance with toxic rules including risk assessments. The Source has to stand on its own in meeting risk levels.
Tox response: Background sampling was conducted outside of the designated census tract in order to directly compare to the samples taken closer to the facility. We follow risk assessment guidance from the Agency for Toxic Substances and

Disease Registry (ATSDR) public health assessment process which does not normalize for background levels and considers risks from exposure to all potential sources in order to appropriately evaluate cumulative health risks for the site-specific conditions.

5. In your monitoring report, you use only extrapolated 24-hour field data for cancer risk and actual cancer data to make conclusions. Why did you not use AERMOD results for lifetime cancers as well? AERMOD results were provided in the companion report by the Colorado Air Pollution Control Division.

Tox response: The AERMOD model is based off of predicted total emissions, which may or may not accurately reflect previous or current conditions surrounding the site. In order to assess health risks from exposure to ethylene oxide in the vicinity of Terumo BCT, targeted air sampling was conducted and averaged over the course of a week. This direct measure of exposure is the most accurate way to represent average exposures to those living in the area surrounding the site to evaluate potential lifetime cancer risk.

6. Your conclusion was that cancers rates were normal but cancer risk was high. It is possible that cancers have yet to show up until 2-3 decades more since the site started in 2001? Why was that not mentioned? The report gives the impression there is no cancer problem. Are we missing something?

Tox response: We do recognize this as a limitation of our cancer rate evaluation, and the limitations were clearly explained at the community meeting and in the Department's brochure on cancer cluster evaluations. Because certain cancers take a lifetime to develop, it could be decades before data would show whether the increased risk is associated with an actual increased rate of cancer. The exact chance of cancer to people exposed to ethylene oxide in the air around Terumo BCT cannot be known. The Department clearly explained at both the community meeting and in the risk evaluation that, based on the monitoring, there may be an excess cancer risk in the community over 26 years of residential exposure. Residential exposure implies 24 hours per day for 350 days per year.

On Tue, Jan 29, 2019 at 11:08 AM Olson, Kyle <Olson.Kyle@epa.gov> wrote:

> Hi Jeremy,
>
> Thanks for the update on phone a moment ago. I'll let you know where the lab is in Research Triangle Park are with the investigation into background levels. If you don't mind sending along the response to the Willowbrook group we'd be grateful, we're just trying to anticipate what might be coming along next with EtO.
>
> If you think of anything you might need from us, especially in the next three weeks, please reach out. We're eager to be useful, especially after the incredible amount of work you all did at CDPHE to look into this.

> Thank you again,
>
> Kyle Olson
>
> Air Program, IATT Unit
>
> US EPA Region 8
>
> 1595 Wynkoop St. 8P-AR
>
> Denver, CO 80202
>
> 303-312-6002
>
> olson.kyle@epa.gov

--

Jeremy Neustifter
Policy Advisor
Environmental Boards and Commissions
Colorado Department of Public Health and Environment

P 303.692.3478 | F 303.691.7702
4300 Cherry Creek Drive South, Denver, CO 80246
jeremy.neustifter@state.co.us | www.colorado.gov/cdphe/

Are you curious about ground-level ozone in Colorado? Visit our ozone webpage to learn more.